Grasustek 6 mg solution for injection in pre-filled syringe
Qualitative and quantitative composition: Each pre-filled syringe contains 6 mg of pegfilgrastim in 0.6 ml solution for injection. The concentration is 10 mg/ml based on protein only. The potency of this product should not be compared to the potency of another pegylated or non-pegylated protein of the same therapeutic class. *Excipients:* Each pre-filled syringe contains 30 mg sorbitol (E 420); Sodium acetate, Polysorbate 20, water for injections. **Therapeutic indications:** Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes). **Posology and method of administration:** One 6 mg dose (a single pre-filled syringe) of pegfilgrastim is recommended for each chemotherapy cycle, given at least 24 hours after cytotoxic chemotherapy. Grasustek is injected subcutaneously. The injections should be given into the thigh, abdomen or upper arm. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Undesirable effects:** *Neoplasms:* Uncommonly myelodysplastic syndrome, acute myeloid leukemia. *Blood, lymphatic system:* Commonly thrombocytopenia, leukocytosis. Uncommonly sickle cell crisis, splenomegaly, splenic rupture. *Immune system:* Uncommonly hypersensitivity reactions including skin rash, urticaria, angioedema, dyspnea, erythema, flushing, hypotension; anaphylaxis. *Metabolism, nutrition:* Uncommonly elevations in uric acid. *Nervous system:* Very commonly headache. *Vascular:* Uncommonly capillary leak syndrome. Rarely aortitis. *Respiratory, thoracic, mediastinal:* Uncommonly acute respiratory distress syndrome, pulmonary adverse reactions (interstitial pneumonia, pulmonary edema, pulmonary infiltrates and pulmonary fibrosis), hemoptysis. Rarely pulmonary hemorrhage. *Gastrointestinal:* Very commonly nausea. *Skin, subcutaneous tissue:* Uncommonly Sweet's syndrome (acute febrile neutrophilic dermatosis), cutaneous vasculitis. Rarely Stevens-Johnson syndrome. *Musculoskeletal, connective tissue:* Very commonly bone pain. Commonly musculoskeletal pain (myalgia, arthralgia, pain in extremity, back pain, neck pain). *Renal, urinary:* Uncommonly glomerulonephritis. *General, administration:* Commonly injection site pain, non-cardiac chest pain. Uncommonly injection site reactions. *Investigations:* Uncommonly elevations in lactate dehydrogenase and alkaline phosphatase; transient elevations in LFTs for ALT or AST. **Legal classification**: POM (prescription only medicine). **Marketing authorisation holder:** Juta Pharma GmbH, Gutenbergstr. 13, 24941 Flensburg, Germany. **Date of revision of text:** 07/2024
Grasustek has been authorised in all countries of the EU as well as in Iceland, Norway, Liechtenstein, United Kingdom. Distribution in Germany, Finland: **medac GmbH Theaterstraße 6; 22880 Wedel**, Germany.